

Commissioner for Patents
March 20, 2006
Page 10

REMARKS

I. Status of the Application

Claims 1-26 were pending in the original application.

In the Office Action, the Examiner: (1) objected to the Abstract; (2) rejected claims 1, 2, 11, and 26 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,152,882 to Prutchi; (3) objected to claims 3-10 and 12-18 as being dependent upon a rejected base claim; and (4) allowed claims 19-25. In this response, the Applicants respectfully amend claims 1, 17, 24, and 26.

II. No New Matter Is Introduced by Way of Amendment

Claim 1 has been amended to require the catheters to be "inserted into the animal in close proximity to, but external to, the animal's heart". Claim 26 has been amended to require the catheters to be "connected to the animal in close proximity to, but external to, the animal's heart". The requirement of the catheters position is supported in the specification at page 7, lines 13-15; page 11, lines 18-20; page 20, lines 16-19; page 26, lines 1-2; and claim 19. Claim 17 has been amended to correct a typographical error, and claims 17 and 24 have been amended for antecedent basis – changing the reference to "ground wire" to "reference lead". Therefore, no new matter has been introduced by way of amendment.

III. Amendment of the Abstract

The Examiner objected to the Abstract stating that the words "The present invention" in lines 1, 2, and 6 should be avoided. Accordingly, Applicants have amended the Abstract and

INDY 1706424v.1

Commissioner for Patents
March 20, 2006
Page 11

believe that the amended Abstract has addressed the Examiner's concern and is therefore allowable.

IV. The Rejection of Claims 1, 2, 11, and 26 Under 35 U.S.C. § 102(b) as Anticipated by Prutchi is Overcome

Claims 1, 2, 11 and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by Prutchi. The Examiner stated that Prutchi, in Figs. 22B and 22C, and as such Figs. 22B and 22C are described in the specification of Prutchi includes "circuits capable of generating pacing pulses 330 and monitoring intracardiac electrograms (IEGMs) ...", and "may comprise N number of leads 386, 384, 382 ... each of which may take the form of a fluid catheter (Fig. 33) equipped with a probe/sensing electrode 608 and a reference electrode 610 ...". The Examiner further stated that because "each lead is equipped with a reference electrode 610, any one of them may perform the function of applicant's claimed 'reference lead', while the other two would perform the function of the 'test leads'." (Office Action, page 3).

Applicants' Invention

Applicants' invention provides a system and method for measurement of electrocardiograms (ECGs) in live subjects. Rather than measure the ECG by skin surface mounted electrodes, such as on the chest of subject, or use of the immobilization technique, the telemetry method, or the recording platform, as is done in the prior art, Applicants' invention measures the ECG through test leads inserted into or a part of intravenous catheters. The catheters of the present invention may be used for other purposes related to tests performed on

INDY 1706424v.1

Commissioner for Patents
March 20, 2006
Page 12

the animal, such as catheters used to carry blood and/or solution to and from the subject, and are generally placed in a vein or an artery. Page 10, lines 20-21; Page 7, lines 7-9.

"The catheters of the invention extend from close proximity to the heart to a point outside the body where they can be connected to test leads." Page 26, lines 5-6. By the use of the system and method of Applicants' invention, ECGs can be measured without requiring that a "device be turned on or off by operator intervention" to permit for continuous sampling (Page 26, lines 18-21); "permits additional monitoring, sample collection, drug infusion, and other tests to be performed on the same animal simultaneously with the collection of the ECGs" (Page 26, line 22 to page 26, line 1); provides "a method of obtaining ECGs from rodents [subjects] that are conscious and unrestrained" (Page 25, line 6-7); "eliminates most of the pain and discomfort caused by the connection of test leads to animals" in other methods (Page 25, line 20-21); and does not require surgery for the implantation of test lead or other devices (such as in the telemetry method). Further, because the test leads of Applicants' invention do not need to be inserted in the heart muscle, the risks associated with such implantation are avoided in Applicants' invention.

The Invention of Prutchi

Prutchi discloses a system and method for chronic measurement of monophasic action potentials ("MAPs"). The system of Prutchi includes "a sensing electrode in contact with cardiac tissue and a reference electrode in proximity to the sensing electrode...". Abstract. As summarized by the Examiner, as shown in Figs. 22B and 22C, and as such Figs. 22B and 22C are described in the specification, Prutchi includes "circuits capable of generating pacing pulses

INDY 1706424v.1

Commissioner for Patents
March 20, 2006
Page 13

330 and monitoring intracardiac electrograms (IEGMs) ...", and "may comprise N number of leads 386, 384, 382 ... each of which may take the form of a fluid catheter (Fig. 33) equipped with a probe/sensing electrode 608 and a reference electrode 610 ...". Further, as shown in Fig. 18, Fig. 19, Fig. 21, Fig. 22A, the lead of Prutchi is "implanted in a transplanted heart" (Col. 26, lines 48-49). More specifically, in Fig. 18, Fig. 19, and Fig. 21, "The distal portion 193 of the lead 190 is inserted into the right ventricle of the heart 200 and contacts the apical ventricular end of the right ventricle." (Col. 26, lines 49-51). In Fig. 22A, "The device 250 includes in implantable housing 252 connected to an implantable lead 60 (best send in FIG. 6). The lead 60 includes a reference electrode 55 and a probe electrode 52. The probe electrode 52 is used for sensing of unipolar intracardiac electrogram (IEGM) signals and MAP signals" (Col. 28, lines 26-32). With regard to Fig. 22B where Prutchi suggests use of multiple leads, it is stated, "Typically, the device 280 includes two leads (N=2) which will be implanted at two different sites of the right ventricle. However, the device 380 may also include a number of leads which is greater than 2 and the lead implantation sites may vary within the heart." (Col. 31, lines 50-54).

Thus, it is clear that Prutchi teaches the use of electrodes for sensing intracardiac electrograms and requires that the electrodes be in contact with and inserted into the heart tissue. Such insertion into the interior of the heart is feasible because the invention of Prutchi is used in heart transplantation – with the heart separable from the subject.

The only reference to measurement of electrocardiogram signals in a live subject is in association with Fig. 20. In the embodiment of Fig. 20, the system includes "the implantable pacing lead 190 shown implanted in a transplanted heart 200 of a patient 227.... The system 220 further includes a plurality of surface electrocardiogram (ECG) electrodes 224 shown to be

INDY 1706424v.1

Commissioner for Patents
March 20, 2006
Page 14

attached to the patient for ECG monitoring.... The analyzer/controller unit further receives ECG signals sensed by the ECG electrodes 224." Col. 27, lines 2-24.

Thus, it is clear that the invention of Prutchi teaches the use of leads implanted in the interior heart tissue for measurement of intracardiac electrograms and MAPs in a transplanted hear, and the use of leads implanted on the skin surface of a live subject for measurement of the ECG of the live subject.

Claim 1 Is Not Anticipated by Prutchi

However, in order to establish that a claim is anticipated by a reference, the reference must teach every element of the claim. MPEP § 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegual Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicant respectfully asserts that the Examiner has failed to establish that independent claim 1 is anticipated by the Prutchi because Prutchi does not disclose every element of claim 1, as further discussed below.

First, Applicants' claim 1 requires "first and second intravenous catheters inserted into the animal". While the Examiner is correct that Prutchi discloses a system that can have multiple leads, the system of Prutchi only includes a single catheter through which one or more leads may pass. For this reason, Prutchi does not disclose, teach or suggest every element of Applicants' claim 1, and the rejection of claim 1 under 35 U.S.C. § 102(b) as anticipated by Prutchi is traversed.

INDY 1706424v.1

Commissioner for Patents
March 20, 2006
Page 15

In addition, Applicants' claim 1, as amended, requires that the first and second intravenous catheters of the device each contain "an electrically-conductive, physiological solution", and that the catheters be "inserted into the animal in close proximity to, but external to, the animal's heart". Test leads are connected to the catheters for the purpose of measuring ECGs. The catheters of Applicants' invention may be inserted into veins and/or arteries for the purpose of conducting other tests, such as an in the allowing for the flow of blood or other fluids to and from the animal. By placement of the catheters in "close proximity to, but external to, the animal's heart", ECGs can be measured from the animal without having to contact the heart of the animal. Unlike Applicants' invention, Prutchi requires placement of a lead in contact with the heart of the animal. Such placement can stress the animal and potentially damage the heart. Further, placement of a lead in contact with the heart as required in Prutchi may not even be possible on a conscious, moving subject.

Because Prutchi does not disclose, teach, or suggest the use of multiple catheters, and does not disclose, teach, or suggest catheters "inserted into the animal in close proximity to, but external to, the animal's heart", but rather Prutchi teaches the use of one or more catheters located within the heart for the purpose of measuring an intracardiac electrogram, it is respectfully submitted that claim 1, as amended, is allowable, and the rejection of claim 1 as anticipated by Prutchi under 35 U.S.C. § 102(b) is overcome.

JNDY 1706424v.1

Commissioner for Patents
March 20, 2006
Page 16

Claims 2 and 11 Are Not Anticipated by Prutchi

Because claims 2 and 11 depend from and include all the limitations of claim 1, as amended, it is respectfully submitted that claims 2 and 11 are allowable, and the rejection of claims 2 and 11 being anticipated by Prutchi under 35 U.S.C. § 102(b) is overcome.

Claim 26 is Not Anticipated by Prutchi

Claim 26, as originally filed, requires a first and second catheter inserted into the animal. Claim 26, as amended, requires that the intravenous catheters of the device be "connected to the animal in close proximity to, but external to, the animal's heart". For the reasons set forth above for claim 1 with regard to the requirement of two catheters and the requirement that the catheters positioned "in close proximity to, but external to, the animal's heart" in Applicants' claim 26, and the absence of any teaching, disclosure, or suggestion of the multiple catheters or the location of catheters external to the heart in Prutchi, it is respectfully submitted that claim 26 is patentable, and the rejection of claim 26 as anticipated by Prutchi under 35 U.S.C. § 102(b) is overcome.

V. Claims 3-10, 12-18, and 19-25 Are Allowable

Claims 3-10 and 12-18 were objected to as being dependent upon a rejected base claim, namely, claim 1. Because claim 1, as amended, is believed to be allowable as discussed above, the objection of claims 3-10 and 12-18 is respectfully overcome, and claims 3-10 and 12-18 are also allowable. The Examiner had already stated that claims 19-25 were allowable.

INDY 1706424v.1

Commissioner for Patents
March 20, 2006
Page 17

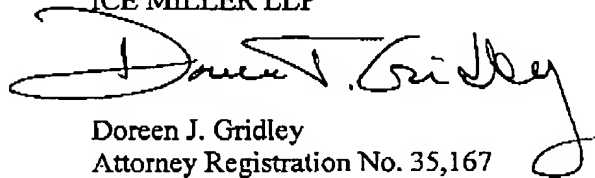
CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the Applicants have made a patentable contribution to the art and that this response places the above-identified application in condition for allowance. Favorable reconsideration and allowance of this application is respectfully requested.

In the event the Applicants have inadvertently overlooked the need for an extension of time or payment of an additional fee, the Applicants conditionally petition therefor, and authorize any fee deficiency to be charged to deposit account 09-0007.

Sincerely,

ICE MILLER LLP



Doreen J. Gridley
Attorney Registration No. 35,167
ICE MILLER LLP
One American Square, Suite 3100
Indianapolis, Indiana 46282-0200
Telephone: (317) 236-2472
Facsimile: (317) 592-4665

Date: 03/20/06

DJG/pgf
Enclosures: Return Postcard

INDY 1706424v.1